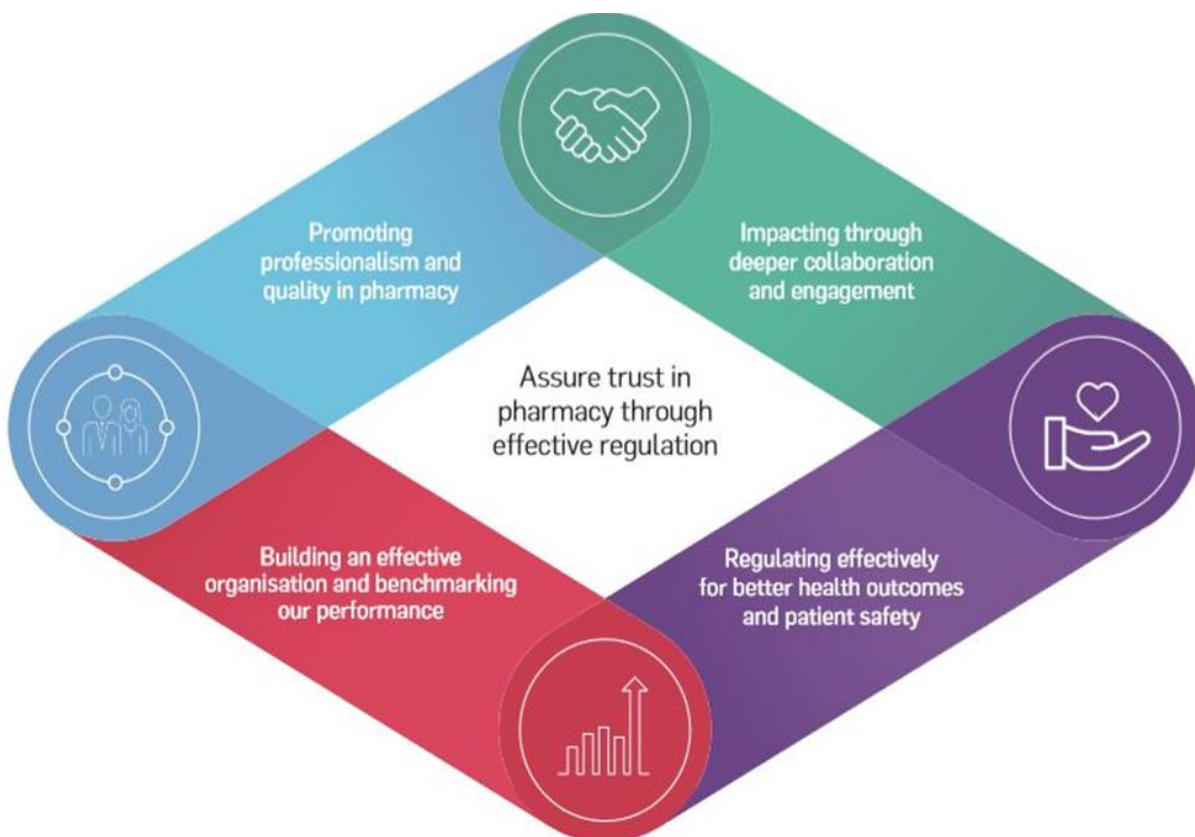


# Report of the Registrar



## Highlights from the Registrar

- Having commenced the process of business and budget planning for 2019 in September, the draft Service Plan and Budget are for decision by Council on 6 December. The Service Plan is designed to further advance the strategic priorities under the Corporate Strategy. The input of PSI staff and of Council members has been important in deciding which, of potentially many, priorities can, and should, be advanced in 2019.
- The Slaintecare Implementation Strategy was published on 8 August. The Registrar and Head of Policy met with the Executive Director responsible for implementation at the Department of Health on 16 October. This was a positive meeting at which we presented the recommendations from PSI's "Future Pharmacy Report", many of which, are relevant to the objectives of Slaintecare.
- The President, the Registrar and two PSI colleagues attended the CLEAR Annual Education Conference in Philadelphia from 25 to 29 September. This was a valuable opportunity to meet and network with fellow regulators (both executive and board/council members) from agencies across the English-speaking world. I am pleased to report that the conference session hosted by our two PSI colleagues on revising our Code of Conduct was selected as the highest rated session in its area at the Conference. I hope to also run a seminar on Regulatory Risk and Organisational Effectiveness next March which will be presented by the Registrar of the Ontario College of Veterinarians who spoke persuasively on this topic at the Conference.
- The first meeting of the Standards Advisory Group for the development of Governance and Accountability Standards for Retail Pharmacy Businesses was held on 20 November. Members of the Group were given an overview of the methodology to be followed as the project progresses, as well as the regulatory context for the development of standards for pharmacies, underpinned by the PSI Corporate Strategy 2018-2020. There was broad consensus in the Group that governance and management structures within retail pharmacy businesses must work to protect the public, and that high standards of leadership and accountability must be practised by those holding key governance positions in retail pharmacy businesses. The next meeting of the Group will be in February.
- We held a Staff Day on 11 October. This was focussed on defining the Service Plan priorities for 2019. We also discussed the importance of being an effective regulator and how our business transformation process will help achieve this. Our new HR Development Manager presented on aspects of the new HR strategy for the organisation with a focus on how best to advance our strategic objectives in 2019.
- Regulatory risk (what it is and how to manage it) is a major issue for all regulatory bodies. We have recently been taking steps in PSI to identify clearly how we manage regulatory risk across all our functions. In combination with the recent appointment of a temporary Project Officer to support our development in this area, we held the first of a two-part, externally-

facilitated workshop on regulatory risk on 22 November, with the second to follow on 12 December. Recent attendance by the Registrar and Head of Regulation at a seminar given by a leading international expert in this field together with a planned seminar in March with the Registrar of the Ontario College of Veterinarians, will also help shape an integrated and effective PSI Regulatory Risk Strategy to be published during 2019. This will be an important strategic result to be achieved under the 2019 Service Plan.

- Key external meetings and events attended by the Registrar since the previous Council meeting:
  - 1 October – Attended the Road Safety Authority’s Annual Academic Lecture
  - 4 October - Meeting with Department of Health (DoH) regarding proposed rules on continuing professional development and on temporary absence.
  - 9 October – Regular liaison meeting with representatives of the Irish Pharmacy Union.
  - 16 October – Meeting with the Executive Director of the Slaintecare Programme Office at the Department of Health.
  - 17 & 18 October – Attended the National Patient Safety Conference at Dublin Castle.
  - 19 October – Meeting with patient advocate and representatives of Epilepsy Ireland regarding medicines containing valproate.
  - 9 November – Meeting at Department of Health with other health professional regulators regarding Brexit and professional recognition.
  - 14 November – Regular liaison meeting between PSI Executive and the CEO and Executive Team from the Health Products Regulatory Authority.
  - 14 November – Attended, with the President, the first “Pharmacy Forum on leading Medication Safety Across Ireland” hosted by TCD School of Pharmacy.
  - 15 November – Met with the Department of Health regarding the draft Code of Conduct.
  - 19 November – Meeting between PSI Executive and the CEO and Executive of the Pharmaceutical Society of Northern Ireland.
  - 19 November – Meeting with the Irish Pharmacy Union to keep the IPU informed as to progress with the re-formulation of the draft rule to regulate what can be done by a Pharmaceutical Assistant in the absence of a registered pharmacist.
  - 20 November – Inaugural meeting of the Standards Advisory Group on the development of Standards for Governance and Accountability in Retail Pharmacy Businesses.

- 21 November - Meeting with the Pharmaceutical Assistants Association to keep the PAA informed as to progress with the re-formulation of the draft rule to regulate what can be done by a Pharmaceutical Assistant in the absence of a registered pharmacist.
- 27 – 29 November – Attended, with the Head of Regulation, a 3-day seminar with Professor Malcolm Sparrow from Harvard, hosted by the Sea Fisheries Protection Authority, on “Becoming an Effective, Risk-Based Regulator”. This was attended by 60 senior representatives from almost 20 different regulatory bodies in Ireland and abroad.
- 5 December – Regular four-monthly governance meeting with the Department of Health.



## Promoting professionalism and quality in pharmacy

We will act to support professionalism within pharmacy and the delivery of safe and reliable pharmacy services.

### Key updates

- 72 pharmacists were selected for the April 2019 Practice Review and notified via email on 4 October 2018. Applications for initial extenuating circumstances closed on 30 October 2018 and all applications have now been reviewed by the Registrar.
- The last year of the National Pharmacy Internship Programme commenced in September with 169 applications submitted and processed. The PSI has reached out to those who have completed the bachelor's Degree Programme in Pharmacy but who have yet to complete the internship programme to notify them of the ending of the National Pharmacy Internship Programme.
- Sumatran Relief<sup>®</sup> (Sumatriptan 50mg tablets) has been authorised as a pharmacy-only medicine for the treatment of migraine which has been previously diagnosed by a doctor. To assist pharmacists in the safe supply of this product, the PSI has produced [Guidance on the Safe Supply of Sumatriptan 50mg tablets](#), which was highlighted by email to all registrants in October. Due to the patient counselling requirements to ensure safe and appropriate use, it is the PSI's guidance that the pharmacist must supply Sumatran Relief directly to the patient.
- [Guidelines on the Sale or Supply of Non-Prescription Medicinal Products from a Retail Pharmacy Business](#) have been approved by the Minister for Health for publishing, as required under Regulation 14 of the Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008). The guidelines are now available to view and download from the [PSI website](#). The profession was informed of the publication of these guidelines via email earlier this month.
- Opioid Substitution Therapy Update; The Misuse of Drugs Regulations 2017 (SI 522 of 2017), allow for the use of buprenorphine containing products as part of Opioid Substitution Therapy. The Opioid Substitution Treatment Prescription Form has been amended to reflect this change. Access to buprenorphine as part of the Opioid Substitution Treatment programme is being introduced by the HSE on a phased basis. Pharmacists were notified of this update in Issue 4 of the PSI newsletter and informed that the principles of clinical governance and safe patient care, as set out in the PSI Guidance for Pharmacists on the Safe Supply of Methadone, apply equally to the supply of buprenorphine products in Opioid Substitution Therapy.

- As part of our ongoing work to promote the recommendations of the Future Pharmacy Report to key stakeholders, the Registrar and Head of Policy met the Director for Slaintecare implementation, Laura Magahy on 11 June. The findings of the report were promoted at the PSI stand at the National Patient Safety Conference 22<sup>nd</sup> & 23<sup>rd</sup> October. The Head of Policy also presented the findings of the report in relation to research at a research meeting held by the IOP in November.
- The Executive have been engaged in the national implementation of the EU Directive on Falsified Medicines and the Delegated Regulations on Safety Features. These Regulations will be effective in Ireland on 9<sup>th</sup> Feb 2018. The Head of Policy and Head of Regulation have attended the regular multi-stakeholder meetings at the DoH. The executive also has regular meetings with the Irish Medicines Verification Office (IMVO) who are tasked with the management of the national repository of safety features for medicines. The PPD unit have issued 2 notifications to pharmacists on the requirements of the regulations and have a PSI webpage with FAQ on the regulations.
- To date, our two APPEL students, have been involved in several projects across different departments in the PSI to gain experience in the type of work PSI carries out.

This has included assisting in work on:

- The Code of Conduct Review project
- Governance and Accountability Standards for a Retail Pharmacy Business
- FAQ document containing information to support a newly registered pharmacist in community pharmacy in Ireland (specifically those registered through the EU or third country route)
- User testing of the PSI website to inform redevelopment of the website next year
- The National Patient Safety Conference
- CLEAR presentation
- Taking part in presentations to first year pharmacy students and at the interprofessional learning meeting on their experience of the 5-year integrated degree program

Both have been a pleasure to work with and will complete their 16-week placement with the PSI on 22 December. Their contribution and fresh perspectives have been invaluable to the ongoing work of the PSI.



## Impacting through collaboration and engagement

We will deepen our engagement and communication with stakeholders to ensure our work is making an impact and that we are focused on the key outcome areas.

### Key updates

- Staff of the Education Unit made presentations to first year MPharm students in all three Schools of Pharmacy during October. The theme of the presentations was 'Introducing the PSI and pharmacy as a regulated profession.'
- A staff member of the Education Unit attended a workshop on Educators of Healthcare Professionals: shared values and activity with a focus on Interprofessional Learning (IPL) delivered by Cardiff University hosted in London on 14 September 2018.
- The Education Unit held a second session with the Interprofessional Learning (IPL) Working Group on 9 October 2018.
- A staff member attended an International English Language Testing System (IELTS) collaborative workshop with other Healthcare Regulators on 15 November 2018.
- The Head of Education and Registration will be presenting to the Cosán<sup>1</sup> Working Group in December to share with the Teaching Council the PSI's experiences of the CPD system for pharmacists since its inception in 2013.
- A member of the I&E Unit attended a Controlled Drug Cross Border meeting on 15 November.
- Staff members including the Registrar attended the Department of Health's Patient Safety Office national patient safety conference in Dublin Castle in October. As well as attending the presentations (not yet made available for sharing), the PSI took a stand to share information, and engage, on ongoing projects including review of the Code of Conduct and Future Pharmacy Practice report, and other work under the current strategy.
- Two members of the PPD Department attended the CLEAR (Council on Licensure, Enforcement and Regulation) Annual Education Conference in Philadelphia to provide a

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<sup>1</sup> Cosán is the national framework for teachers' learning developed by the Teaching Council of Ireland.

workshop on 'Creating a Code of Conduct for Modern Pharmacy Practice'. The workshop was very well received with plenty of engagement from the audience especially around how to get meaningful engagement from stakeholders during the development phase and how a Code of Conduct should be used alongside the legislation to make professional decisions in the interest of patient care. The PPD department was informed in early November that its session has been selected as the highest rated session for the Administration, Legislation, and Policy track at the 2018 CLEAR Annual Educational Conference and will be formally recognised with an Honourable Mention in the next issue of CLEAR News. The PPD department has also been invited to present a webinar on this topic by CLEAR.

- PSI staff member provided a presentation for a College of Psychiatrists of Ireland CPD event. The presentation focused on changes to the Misuse of Drugs legislation made in 2017 and raised awareness of the Medical Council and PSI joint guidance on controlled drugs for doctors and pharmacists published last October. The discussion examined issues in the practical implementation of the Controlled Drugs legislation. There was excellent engagement on the topic at the event, with useful discussion on matters impacting patient care.
- The PSI assisted the HPRA in communicating with pharmacists to advise them that there is a global intermittent supply of adrenaline auto-injectors (AAIs) that may impact the Irish market. This was highlighted to all pharmacists in Issue 4 of the PSI newsletter. To help ease the demand on AAIs the PSI reminded pharmacists providing the flu vaccination service of the stock requirements for adrenaline in case of anaphylaxis, as set out in the PSI Guidance, which is in line with NIAC guidelines. Pharmacists were also reminded that if they have completed the necessary training through IOP/Hibernian Healthcare and have valid training certificates, they can administer adrenaline using adrenaline vials in cases of anaphylaxis following vaccine administration.
- We continue to work on building our profile on social media and to provide information on regulatory and public health updates. Recent posts included the PSI's online video resources, engagement with pharmacy students, and the PSI's Patient Charter. We also support relevant content from other organisations using our social media platform. We recently promoted the HPRA's health campaign on patient reporting of side effects to medicines, and the World Health Organization's antibiotic awareness week campaign. We have 526 followers on Twitter, an increase of 19% since the September Council meeting, and 223 followers on LinkedIn, an increase of 14% since the September Council meeting. We



## Regulating effectively for better health outcomes and patient safety

We will regulate in ways that are proportionate, effective and risk-based, with a focus on the key areas relevant to patient health and safety.

### Key updates

- At its meeting on the 20 September, the Council approved the recommendations arising from the review of the Pharmacy Assessment System. Registrants have been notified of Council's decision, including the reduction in the requirement to complete the Pharmacy Assessment System to once per year.
- PSI Authorised Officers (Pharmacy Inspectors) conducted twenty-three inspections of pharmacies in collaboration with the Health Products Regulatory Agency (HPRA). The purpose of these visits was to review the supply and management of prescription medicines and controlled drugs,
- One inquiry was concluded by means of mediation since the last Council meeting. The mediation took place on 12 October, which was within 7 weeks of the Preliminary Proceedings Committee's decision to refer the matter for further action. The mediation was successfully concluded over one day and is before Council for noting at their meeting on 6 December 2018.
- An appeal against the proportionality of a sanction imposed on a registered pharmacist was heard before the High Court on 18 October. In light of the particular circumstances of the case, which included a finding of impairment, the President of the High Court amended the sanction imposed. The change was due to the fact that the registered pharmacist was able to demonstrate, due to the passage of time, that their health had improved and that they were currently not impaired to work as a pharmacist. On that basis alone, the President amended the sanction of erasure to that of conditions. Ultimately 18 conditions were imposed on the respondent pharmacist's registration.
- A workshop with Professor Liam Delaney of UCD took place with a number of PSI staff on the 24<sup>th</sup> of October to explore a behavioural insights programme of work at the PSI. The outputs from this workshop will be considered at a follow-up workshop with staff before Christmas so that certain initiatives can commence in 2019.
- Two temporary Regulatory Project Pharmacists (x 2) have commenced their work in the Regulation Department. Posts will plan, coordinate and deliver on the following key strategic activities which the PSI is committed pursuing as part of its 2018 Service Plan:

- Develop a risk assessment framework to assist with the effective deployment of regulatory resources together with an associated implementation plan and pilot of new framework.
  - Design the PSI's programme of themed reviews across key areas of pharmacy practice and develop and implement the associated piloting of this approach as part of the PSI's compliance activities.
- Several PSI staff have been engaged with the Department of Health to assist in the progression of regulations in relation to implementation of the proposed national cannabis access programme, the implementation of the EU delegated regulations on safety features and updating the medicinal products regulations to assist in the implementation of the forthcoming legislation on termination of pregnancy.
- A training/development day for the Council was held on 25 October as part of ongoing development and learning for the Council in meeting its regulatory responsibilities. It included an interactive presentation and workshop with Mr. Leslie Cuthbert on communication techniques, fact finding and questioning in the context of hearings and inquiries, as well as a discussion on strategic planning for 2019, and overview of the developments in the revision of the Code of Conduct.



## **Building an effective organisation and benchmarking our performance**

We will build an agile and high-performing organisation, capable of delivering on our mission and have our performance independently assessed.

### **Key updates**

- The Head of Education and Registration and Education Unit staff member attended an EFQM conference in Vienna in October with a view to aiding the PSI to pursue accreditation under this organisational excellence framework in 2019.
- A draft HR Strategy for the PSI has been developed by the HR Development Project Manager working with the CEO and the Head of Operations and has been presented to the Executive Leadership Team. The draft HR strategy, entitled Building Capability through People, seeks to support the organisation in delivering the PSI Corporate Strategy and presents an overarching HR agenda for the PSI from 2018-2020. It builds on the strengths of the PSI and will enable the organisation to build capability through people in a consistent and transparent way, support our people through any change arising from the Corporate Strategy whilst embedding strategic HR competency as a key business process. Building Capability through People is based on three strands:
  - Attracting, developing and retaining talent
  - Making the PSI an employer of choice
  - Enhancing transparency in HR
- As part of the HR Strategy's second strand, 'Making the PSI an employer of choice', the PSI is launching a staff engagement survey prior to Christmas 2018. The survey is mapped to the Civil Service Survey and an employee working group participated heavily in its design. The survey will be administered again in 6 months' time (mid-2019) and regularly thereafter and it is hoped it will provide a strong insight into the pulse of the organisation.
- We continued to engage closely with the Department of Health regarding sanction for the 15 new posts, the business cases for which were submitted in March 2018. It appears that seven may be sanctioned in 2018, with the balance in 2019 and correspondence to this effect is in train.
- Following a mini-tender process, BDO Eaton Square has been selected to work with the design team comprising PSI senior management to progress the first stage of the review of the PSI's organisation structure. This process is expected to conclude by end January 2019. The review and adaptation of our organisation and management structures is a key action in

the Corporate Strategy 'to support the delivery of our strategic objectives and to enable us to manage all corporate and regulatory risks effectively'.

- Staff training initiatives progressed including:
  - Several members of the I&E Unit have attended advanced Excel training with IACT, with more staff, from the I&E Unit and Legal Affairs Unit, to attend training sessions in December.
  - Four-day Project Management Professional (PMP) training course with Velopi attended out by our ICT Officer
  - Customer Relationship Management (CRM) software 3-day course attended by our ICT Administrator
- Following receipt of the final report on PSI's IT Security Assessment conducted by Ward Solutions, all critical/high risks and recommendations have been resolved, including the two critical risks. Ward Solutions are scheduled to commence the re-testing of all the critical/high risks with the final report to be issued by mid-December 2018.
- Following the approval of the business case by Council to proceed with the Business Transformation Project, the programme has commenced with engagement by staff with process re-design and development of required documentation for the initial testing of the market to identify interested vendors.
- To raise awareness among our staff of our individual and organisational impact on the environment and ways we can alter our behaviour to minimise this impact, the PSI's Workplace Safety & Environmental Sustainability Committee, with the assistance of our pharmacy students on placement, organised a series of events as part of Global Climate Change Action Week at the PSI, from the 24-31 October. The findings from a staff survey administered during this week on actions we can take as an organisation to minimise our impact will be presented by the pharmacy students at the 29 November meeting of the Workplace Safety & Environmental Sustainability Committee.

## Appendix 1 –Statistical Summary

### Fitness to Practise (figures as at 29 November 2018)

#### Fitness to Practise Concerns

Total concerns received in 2018	120
New concerns received since last report date	24
Open concerns	14*
Concerns reviewed since last report date	31

\* This figure may include concerns received prior to 2018 which are still under review

#### Fitness to Practise Complaints for Screening Committee (PPC)

Total complaints received in 2018	48
New complaints received since last report date	14
Open complaints	22*
Complaints considered by PPC since last report date	11**

\* This figure may include complaints received prior to 2018 which are still being processed

\*\* 81% of which met KPI of PPC decision being made within six months i.e. from when the complaint was received to when the PPC made a final decision

#### Inquiries

Heard year to date	8*
Heard since last report	3**
Cases being investigated/prepared for hearing	16***

\* (7 – PCC & 1 - Health Committee). This figure may include inquiries which were commenced in 2017 but concluded in 2018 and which may relate to multiple complaints and/or respondents

\*\* (3 - PCC). Inquiry KPI timeline met in two inquiries i.e. both inquiries held within two years from when the complaint was received. The third inquiry was held within 2 years and 1 week from when complaint was received.

\*\*\* (15 – PCC & 1 - Health Committee)

#### Mediation

Heard year to date	1
Heard since last report	1
Cases being prepared for mediation	0

#### Sanction Hearings/ Undertakings/Dismissals before Council\*

Heard year to date	12
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Cases being prepared for Council Meeting on 6 December	3
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\* This figure is reported on a per respondent basis

### High Court Sanction Confirmation Hearings\*

Heard year to date	4
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\* This figure is reported on a per respondent basis

### Suspension Applications

Two applications have been made to the High Court year to date

### Appeal

One Appeal was heard before the High Court

### Professional Registration (figures as at 29 November 2018)

- The bulk of continued registration period (for registration certificates expiring at the end of Dec 2018) is ongoing. Hard copy continued registration applications processed to date are 219 and online applications processed to date are 4034.
- 7 alerts have been issued to date this year under the Internal Market Information system to other EU Competent Authorities responsible for the implementation of the provisions of the Professional Qualifications Directive as it pertains to pharmacists.
- 13 EPCs for establishment of service have been processed (new European route of entry to recognition and registration) – 10 EPCs have been granted, and 3 are in process.
- 49 Certificates of Current Professional Status have been issued to date.
- 17 Restoration applications have been processed to date.
- 108 Voluntary Cancellation applications and 25 Involuntary Cancellations have been processed to date.
- 11 EU/TCQR Registration meetings held to date this year.
- 30 TCQR recognition applications received to date this year.
- 124 EU recognition/registration applications received to date this year.

### Regulation of Retail Pharmacy Businesses

Registration of Retail Pharmacy Businesses	
Number of Registered Retail Pharmacy Businesses as of 30/11/2018	1943
Number of Retail Pharmacy Businesses Registered in 2018	118
Number of Retail Pharmacy Businesses Cancelled in 2018	105
Number of Changes in Supervising and Superintendent Pharmacists in 2018	465

<b>Internet Supply (as of 30/11/2018)</b>	
Number of Pharmacies on Part A	51
Number of Non-Pharmacies on Part B	81

<b>Investigation Activity (Part 7 / Inspection &amp; Enforcement)</b>		
No of investigations open	No of investigations initiated since the last Council meeting	No of investigations closed since the last Council meeting
25	0	2
Investigation Fieldwork Activity (Section 67) – <i>Interviews / Statements / Pharmacy Visits</i>		34

<b>Inspection Activity (as of 30/11/2018)</b>	
Number of Registration-related Inspections (Section 19)	102
Number of pharmacy inspections (Section 67) <ul style="list-style-type: none"> <li>- 114 Inspections – including 53 systems / routine inspections, 30 risk-based inspections, 23 joint inspections with the HPRA and 8 joint inspections with the HSE</li> <li>- 19 Re-inspections – including re-inspections following the Registrar’s decision under Section 71(1)(d)</li> <li>- 7 Thematic Inspections – including 6 Flu vaccination inspections and 1 Internet Supply inspection</li> </ul>	140
Number of pharmacy assessment system review visits, including a review of the pharmacy’s awareness of the updated patient safety information for Valproate-containing medicines	101